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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,912	01/30/2004	Carl Ernest Alexander	4506-1025	2239

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/766,912	ALEXANDER ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7,8,10,11,13,18,23-31 and 34* is/are pending in the application.

4a) Of the above claim(s) *10,11,18,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 7, 8, 13, 23-28, 30, and 34* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments in the Appeal Brief, filed October 25, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

In view of the Appeal Brief filed on October 25, 2010, PROSECUTION IS HEREBY REOPENED. New Rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (see end of the action):

Claims

Claim Objections

Claims 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The independent claim recites agar has a concentration ranging from 0.5 to 1.2% by weight. The dependent claims 3 and 4 recite "0.1 to about 2% by weight" and "0.3 to about 0.95% by weight" respectively. Therefore the dependent claims do not further limit the range recited by independent claim 1.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 13, 23, 27, 30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolten et al. (US 4,814,179) as evidenced by Athanikar (US 6,379,651).

Bolton et al. disclose sustained release gel tablets. The compositions comprise a gelling agent, oil, a therapeutic agent and water (Abstract). Therapeutic agents include analgesics and tetracycline, which may be used in the treatment of dental conditions (as evidenced by Athanikar US 6,379,651). The gelling agent comprises 0.5 to 4% of the gel tablet and includes agar and carageenan (col. 4, lines 1-13), encompassing instant claims 1, 30 and 34. The tablets are made by 1) preparing a solution of the hydrocolloid gelling agent and excipients, if any, in hot water; 2) preparing a mixture of a therapeutic agent and a therapeutically acceptable inert oil; 3) cooling the solution of gelling agent, but not to the point where gelation takes place, and combining the solution and the mixture from step (2) with stirring, while maintaining the temperature above the gelation temperature; 4) pouring the mixture from step (3) into a tablet mold and allowing it to stand in the mold to form a gel; and 5) drying the molded gel tablets to reduce the water content, encompassing claim 1, 23 and 30. The Example 9 comprises ampicillin (an antibiotic used in dental compositions to treat conditions of the oral cavity, as evidenced by Athanikar US 6,379,651, col. 5, 46-55), agar and water, and the tablet has a final mass of about 423 mg, encompassing claims 1, 8, 27 and 30. The compositions may also comprise conventional additives and excipients such as surfactants, preservatives, bulking agents and antioxidants (col. 4, lines 28-30).

The instant specification discloses that similes for the term “bead” includes tablet (page 3, paragraph 5). Therefore the disclosure of a gel tablet in Bolten et al. reads on the recitation of "gel bead" by the instant claims.

In regard to the gel framework breaking apart, this appears to be based on the amount of gelling agent used. The reference discloses the gelling agent comprises 0.5 to 4% of the gel tablet and the claims recite 0.5 to 1.2%. Thus the gel tablet should have the property of breaking apart when disrupted by a person in a personal oral or dental procedure.

In regard to claim 7, the compositions comprise actives that are used in dental care, such as ampicillin, and may also comprise surfactants. Therefore the reference meets the limitation of the bead comprising a dentifrice.

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 3, 4, 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolten et al. (US 4,814,179) as evidenced by Athanikar (US 6,379,651) as applied to claims 1, 7, 8, 13, 23, 27, 30 and 34.

Bolten et al. as evidenced by Athanikar is discussed above and discloses that the gel tablets comprise a gelling agent with a concentration ranging from 0.5 to 5% by weight of the composition. The reference differs from the instant claims insofar as it does not disclose the end points recited in claims 3, 4, 24, 25 and 28.

The prior art does not disclose the exact claimed values of 0.1 to about 2 percent as recited in claim 3, 0.3 to about 0.95 as recited in claim 4, 0.1% by weight to 2% by weight as recited in claim 24, 0.3% by weight to 0.95% by weight as recited in claim 25, and 0.7 percent by weight to 0.9 percent by weight as recited in claim 28 but does

overlap disclosing 0.5 to 4%: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

2) Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bolten et al. (US 4,814,179) as evidenced by Athanikar (US 6,379,651) as applied to claims 1, 3, 4, 7, 8, 13, 23-25, 27, 28, 30 and 34 above, in further view of Huang et al. (US 6,485,738).

Bolten et al. as evidenced by Athanikar is discussed above and discloses that the gel tablets may be used to deliver vitamins. The tablet also comprises oil and therapeutic agents (Abstract). The reference differs from the instant claim insofar as it does not disclose the compositions comprise gelatin.

Huang et al. disclose gel delivery compositions for promoting bioavailability of vitamins (Abstract). Agar is preferred to pectin because its smaller molecular structure helps in absorption of the delivered component. The gelatin/agar base provides a flexible base that can cover a full range of consistencies, from spoonable suspension to a rigid gel. The base provides a stable environment for both water and lipid soluble substances. The bioavailability enhancing substance is preferably a surfactant such as a mixture of lecithin and Vitamin E which promotes absorption of the carried substance. Other ingredients, such as flavoring agents, coloring agents or thickeners, among others, can be incorporated in the present invention (col. 2, lines 6-15). Components such as calcium glycerophosphate are used and reduce dental caries (col. 5, lines 65-

67). Ingredients such as drugs may also be incorporated into the gels (col. 5, lines 9-12). The ratio of agar to gelatin varies form 0.5 to 1 to 2.5 to 1 (col. 7, line 33-35).

The reference differs from the instant claim insofar as it does not disclose the recited amounts of agar and gelatin nor does it disclose the gels are beads that break apart, although it does disclose the compositions may be rigid gels.

It would have been obvious to one of ordinary skill in the art to have added gelatin to the compositions of Bolten et al. comprising agar, motivated by the desire to formulate a base for the gel tablet that provides a stable environment for both water and lipid soluble substances, as disclosed by Huang et al.

Bolten et al. disclose the amount of gelling agent ranges from 0.5 to 4% by weight. Huang et al. disclose the ratio of agar to gelatin ranges from 0.5:1 to 2.5:1, which would encompass 0.2 to 8% by weight of gelatin calculated from the amount of gelling agent when used in the compositions of Bolten et al. and the ratio disclosed by Huang et al. The prior art does not disclose the exact claimed values of 1% by weight to 4% by weight gelatin but does overlap disclosing 0.2% to 8% (based on the above ratio): in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

3) Claims 1, 3, 4, 7, 8, 13, 23-25, 27, 28, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delrieu et al. (US 2002/0086042), as evidenced by Athanikar (US 6,379,651).

Delrieu et al. disclose crushable gel beads formed of an agar complex to provide novel cosmetic, pharmaceutical, etc. delivery vehicles for topical delivery of biologically or cosmetically active agents. Actives are dispersed throughout the beads and may be bound to a restraining polymer (Abstract), encompassing claims 1 and 23, 24 and 25. Agar can be formed into beads of various sizes for delivery of actives such as pharmaceutical drugs or even biological cells (paragraph 0008). Polymers that may be used as the restraining polymer includes karageenan (carageenan) (paragraph 0068), which encompasses claims 30 and 34. The agar complex beads can be formed in various sizes to deliver actives, including pharmaceutical drugs or even biological cells, to the skin and applied to the skin as soft crushable beads (paragraph 0026). Based on the examples, the amount of agar in the bead is 1.5% by weight of the bead (see Examples), encompassing claim 3 and 24. Preferably the solids comprise from about 0.5 to about 40 percent by weight of the solution or dispersion and more preferably from about 1.5 to about 25 percent by weight. The relative proportion of restraining polymer to agar can be as low as 1:10, but to obtain a satisfactory loading of active agent a proportion of at least 1:1, up to about 10:1 restraining polymer to agar, is desirable. Preferably, a proportion of from about 2:1 to about 6:1 is used (paragraph 0084). Depending upon the potency of the active and other factors such as its physical form, the proportion of active agent to restraining polymer may range from about 0.01:1 to about 10:1, preferably from about 0.1:1 to about 5.0:1. Preferably also, the active agent comprises from about 0.01 to about 20 percent of the solution, or dispersion, at the injection needle, more preferably about 0.1 to about 10 percent (paragraph 0085). The

beads may be used to deliver actives to the teeth or other accessible endogenous body surfaces can be similarly targeted, depending upon the active and the cosmetic or medicament vehicle into which the beads are formulated (paragraph 0035). Actives include polyphenols, antibacterials such as glucose oxidase, which are components used in oral compositions as anti-plaque agents as evidenced by Athanikar (col. 7 lines 20-30), encompassing claims 7, 8 and 13.

The reference differs from the instant claims insofar as it does not disclose the beads have a mass between 0.25 and 2.0 grams.

In regard to the mass of the beads, the reference discloses that the agar complex beads can be formed in various sizes to deliver actives, including pharmaceutical drugs or even biological cells, to the skin and applied to the skin as soft crushable beads (which read on break apart) (paragraph 0026). The composition may deliver actives not only to the skin but also to teeth tissue (paragraph 0035). The solids comprise from about 0.5 to about 40 percent by weight of the solution or dispersion. The relative proportion of restraining polymer to agar can be as low as 1:10 to up to about 10:1 restraining polymer to agar (paragraph 0084). Depending upon the potency of the active and other factors such as its physical form, the proportion of active agent to restraining polymer may range from about 0.01:1 to about 10:1. Preferably also, the active agent comprises from about 0.01 to about 20 percent of the solution, or dispersion (paragraph 0085). The active is a result effective variable and its desired amount would depend on the desired application and desired result. One of ordinary skill in the art would reasonably conclude that the mass of the bead would determine how much active may

be incorporated into the bead. It would have taken no more than the relative skill of one of ordinary skill in the art to have made the beads of Delrieu et al. having a mass of between 0.25 to 2.0 grams motivated by the desire to make a bead that delivered the desired amount of active for the desire therapeutic application while maintaining the proportions disclosed by Delrieu et al. See MPEP 2144.05.

Delrieu et al. does not disclose the exact endpoints as recited in claims 1, 3, 4, 24, 25, 28, 30 and 34 but does disclose the proportion of solids in the compositions, which would include the gelling agent, the restraining polymer and the active. The solid preferably make up 1.5 to about 25 percent by weight of the composition. The relative proportion of restraining polymer to agar can be as low as 1:10 to up to about 10:1 (paragraph 0084). The proportion of active agent to restraining polymer may range from about 0.01:1 to about 10:1. Based on these ranges and the amount of solids in the disclosed compositions, the amount of agar disclosed by Delrieu et al. encompasses the amounts of the instant claims. The prior art does not disclose the exact claimed values of 0.5 to 1.2; 0.1 to 2%; 0.3 to about 0.95%; and 0.7 to 0.9, by weight agar as recited in claims 1, 3, 4, 24, 25 and 28 and 0.1 to 4% carrageenan as recited in claims 30 and 34, but does overlap, for example when the agar, restraining polymer and active are in a ratio of 1:1:1, the amount of agar ranges from 0.5% to 8.3% and the amount of carrageenan ranges from 0.5 to 8.3: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Response to Declarations

Declaration by Carl Ernest Alexander

The Declaration filed by Carl Ernest Alexander is not persuasive to overcome the new rejections as set forth above. The declaration discloses a comparison of the beads of the instant claims and the compositions of the teachings of the combination of Schmidt, which discloses single dose toothpaste films, and Grossmith. The new rejections are based on references that disclose gel beads or tablets formed form agar and comprise amounts of agar overlapping that recited by the instant claims. Therefore the comparison disclosed in the Declaration do not apply to the compositions disclosed by the presently cited prior art.

Declaration by Patrick Joseph Silcock

The Declaration filed by Patrick Joseph Silcock is not persuasive to overcome the new rejections as set forth above. The declaration discloses a comparison of the beads of the instant claims and those made from the reference of Schmidt, which discloses single dose toothpaste films. The new rejections are based on references that disclose gel beads or tablets formed form agar and comprise amounts of agar overlapping that recited by the instant claims. Therefore the comparison disclosed in the Declaration do not apply to the compositions disclosed by the presently cited prior art.

Obvious-Type Double Patenting

Claims 1, 3, 4, 7, 8, 13, 23-28, 30 and 34 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of copending Application No. 12/067817.

This rejection is maintained pending appropriate action by applicant.

Claims 1, 3, 4, 7, 8, 13, 23-28, 30 and 34 are rejected.

Claims 10, 11, 18, 29 and 31 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612